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PROSPECTIVE OBSERVATIONAL STUDY ON ULTRASONOGRAPHY'S ROLE IN PREDICTING PREGNANCY OUTCOMES DURING THREATENED ABORTION.

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ABSTRACT

Background

Threatened abortion, characterized by vaginal bleeding in early pregnancy with a closed cervix, presents a common challenge in obstetrics. Ultrasonography has emerged as a pivotal tool for assessing this condition, offering valuable insights into pregnancy outcomes. Understanding its predictive value is crucial for clinical decision-making and patient support. The study aimed to assess the effectiveness of ultrasonography in predicting pregnancy outcomes among women presenting with symptoms of threatened abortion.

Methods

A total of 160 pregnant women aged 18 years and above, with gestational ages between 6 to 12 weeks, were included in the study. Clinical data, obstetric history, and ultrasonography findings were recorded. Participants were followed up to determine pregnancy outcomes. Statistical analysis, including logistic regression, was performed to assess the association between ultrasound findings and pregnancy outcomes.

Results

Among the participants, 92.5% had ultrasound-confirmed viable pregnancies, while 7.5% had non-viable pregnancies. The absence of fetal heartbeat on ultrasound was significantly associated with a higher risk of miscarriage ($p < 0.001$). Notably, no cases of ectopic pregnancy were observed. The majority of pregnancies (87.5%) resulted in live births.

Conclusion

Ultrasonography plays a pivotal role in predicting pregnancy outcomes in cases of threatened abortion. The absence of fetal heartbeat on ultrasound is a strong predictor of miscarriage, aiding clinical decision-making. These findings underscore the importance of early and accurate ultrasound assessment in managing and reassuring women facing threatened abortion.

Recommendations

Further research is warranted to refine risk assessment models and explore additional factors influencing pregnancy outcomes in threatened abortion cases.

Keywords: *Threatened abortion, ultrasonography, pregnancy outcomes, miscarriage, predictive value.*
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INTRODUCTION

Ultrasonography has become an indispensable tool in the field of obstetrics, particularly in the assessment and management of threatened abortion. Threatened abortion, defined as vaginal bleeding during the first 20 weeks of gestation with the cervix remaining closed, is a common complication affecting approximately 20% of all recognized pregnancies [1]. The uncertainty associated with this condition can be distressing for expectant mothers, making accurate diagnosis and prognosis crucial.

The role of ultrasonography in this context is multifaceted. It is primarily used to confirm intrauterine pregnancy, evaluate fetal viability, and assess for any abnormalities that might contribute to the bleeding [2]. One of the key aspects of ultrasonography in threatened abortion is its ability to predict pregnancy outcomes. Studies have shown that certain sonographic findings, such as the presence and size of a subchorionic hematoma, fetal heart rate, yolk sac appearance, and crown-rump length, can be significant predictors of pregnancy outcome [3].

For instance, a diminished fetal heart rate below the 5th percentile for gestational age is a strong predictor of miscarriage in cases of threatened abortion. Similarly, the presence and size of a subchorionic hematoma have been associated with an increased risk of miscarriage, preterm labor, and placental abruption [4]. The size of the hematoma, particularly when it exceeds 25% of the chorionic sac size, has been correlated with a higher risk of adverse pregnancy outcomes [5].

Moreover, ultrasonography plays a crucial role in ruling out ectopic pregnancy, which is a vital differential

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diagnosis in cases of threatened abortion. The ability to visualize an intrauterine pregnancy effectively excludes an ectopic pregnancy in most cases.

The study aims to evaluate the efficacy of ultrasonography in predicting pregnancy outcomes in cases of threatened abortion.

METHODOLOGY

Study Design

This prospective observational study aims to assess the predictive value of ultrasonography in predicting pregnancy outcomes among women presenting with threatened abortion. By examining a cohort over time, the study seeks to understand how early ultrasound findings correlate with pregnancy viability and outcomes, providing valuable insights for clinical management and patient counseling in obstetrics.

Study Setting

The study was conducted at KEM Hospital, Pune, Maharashtra, India, between July 2022 and August 2023

Participants

Out of the 200 women screened, 160 met the inclusion criteria and consented to participate. These participants were selected based on clinical signs of threatened abortion, gestational age between 6 to 20 weeks, and absence of known adverse pregnancy outcomes at the time of enrolment. The selection process involved reviewing medical records and consultations in the hospital's obstetrics department.

Inclusion Criteria

- Age 18 years and above.
- Gestational age between 6 to 12 weeks.
- Clinical presentation of vaginal bleeding or abdominal pain suggestive of threatened abortion.
- Willingness to provide informed consent to participate in the study.

Exclusion Criteria

- Pregnant women below 18 years of age.
- Women with known chromosomal or structural fetal anomalies identified before the study
- Those with severe pre-existing medical conditions like uncontrolled diabetes or chronic hypertension

Sample Size

The sample size was 160 participants, determined based on the expected prevalence of threatened abortion and desired confidence and precision levels for estimating the association between ultrasonography findings and pregnancy outcomes. The sample size was determined using a power analysis, aiming for a power of 80% and an alpha level of 0.05, to detect significant differences in pregnancy outcomes based on ultrasonography findings. This size also accounts for an anticipated dropout rate of 10%, ensuring sufficient data for robust statistical analysis.

Bias

Efforts were made to minimize selection bias by recruiting consecutive eligible patients. Potential sources of bias were addressed through standardized data collection procedures and statistical analysis.

Variables

Key variables included ultrasonography findings (e.g., fetal viability, gestational age, fetal heart rate, abnormalities), pregnancy outcome (e.g., miscarriage, ectopic pregnancy, successful continuation of pregnancy), demographic information (age, parity, medical history), obstetric history (previous pregnancies and complications).

Data Collection

Demographic and obstetric data was collected through structured interviews. Ultrasound findings were documented by qualified sonographers or obstetricians. Follow-up data on pregnancy outcomes was recorded. Participants received standard clinical care for threatened abortion, including appropriate medical interventions, as determined by their healthcare providers.

Ultrasound Examination

All participants underwent transvaginal or transabdominal ultrasound examinations performed by qualified sonographers or obstetricians. Ultrasonography findings included fetal viability, gestational age, fetal heart rate, and any visible abnormalities.

Statistical Analysis

Descriptive statistics summarized demographic data and ultrasonography findings. Binary logistic regression analysis determined the association between ultrasonography findings and pregnancy outcomes. Statistical significance was set at $p < 0.05$.

Ethical considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

RESULT

A total of 160 pregnant women presenting with symptoms of threatened abortion were enrolled in the study. The mean age of participants was 29.5 years (± 4.2), with ages ranging from 18 to 42 years. The majority of participants were primigravida (53.8%), while 46.2% had one or more previous pregnancies. The mean gestational age at enrolment was 8.2 weeks (± 1.5), with a range of 6 to 12 weeks.

Among the 160 participants, 148 (92.5%) showed ultrasound-confirmed viable pregnancies, with detectable fetal heartbeats. The remaining 12 (7.5%) participants displayed non-viable pregnancies with no detectable fetal heartbeats. The mean gestational age as determined by ultrasound was 8.4 weeks (± 1.4), ranging from 6.2 to 11.9 weeks. The mean fetal heart rate was 150 beats per

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minute (bpm) (± 9.7), with a range of 135 to 170 bpm. Among the ultrasound findings, 22 participants (13.8%) displayed various abnormalities, including subchorionic hemorrhage (n=10) and cervical incompetence (n=12).

Table 1: Maternal and neonatal outcomes

Outcome Category	Number of Cases
Maternal Outcomes	
- Miscarriage	20 (12.5%)
- Successful Continuation	140 (87.5%)
Neonatal Outcomes	
- Live Births	140 (87.5%)
Ultrasound Results	
- Viable Pregnancies	148 (92.5%)
- Non-Viable Pregnancies	12 (7.5%)
- Gestational Age (weeks)	Mean: 8.4
- Fetal Heart Rate (bpm)	Mean: 150
- Abnormalities Detected	22 (13.8%)

During the follow-up period, 20 participants (12.5%) experienced miscarriage, with gestational ages at the time of miscarriage ranging from 7 to 11 weeks. The majority of miscarriages occurred within two weeks of enrolment. There were no cases of ectopic pregnancy observed in this study, indicating that all pregnancies were intrauterine. The majority of participants, 140 (87.5%), had a successful continuation of their pregnancies, resulting in the delivery of healthy infants. The gestational ages at delivery ranged from 38 to 41 weeks.

Binary logistic regression analysis revealed a statistically significant association between non-viable ultrasound findings (absence of fetal heartbeat) and the likelihood of miscarriage ($p < 0.001$). Participants with non-viable ultrasound findings were 15 times more likely to experience a miscarriage compared to those with viable pregnancies, after controlling for age, parity, and gestational age. Subgroup analysis did not demonstrate a significant impact of specific ultrasound abnormalities (sub chorionic hemorrhage or cervical incompetence) on pregnancy outcomes ($p > 0.05$). This suggests that the presence of these abnormalities alone did not significantly increase the risk of miscarriage in this cohort.

DISCUSSION

The results of this prospective observational study involving 160 pregnant women with threatened abortion symptoms revealed several noteworthy findings. The majority of participants (92.5%) displayed viable pregnancies, as confirmed by ultrasound, while 7.5% had non-viable pregnancies. Approximately 12.5% of participants experienced miscarriage during the study period, with no cases of ectopic pregnancy observed. Notably, the absence of a fetal heartbeat on ultrasound was strongly associated with an increased risk of miscarriage, with affected participants being 15 times more likely to undergo this outcome.

Subgroup analysis did not identify a significant impact of specific ultrasound abnormalities on pregnancy outcomes, suggesting that the presence of sub chorionic hemorrhage or cervical incompetence alone did not significantly increase the risk of miscarriage in this cohort. These findings underscore the importance of early ultrasound assessment in cases of threatened abortion for accurate identification of non-viable pregnancies, enabling appropriate clinical management and counseling for patients.

A series of studies have explored various factors influencing pregnancy outcomes in cases of threatened abortion. A study assessed the clinical value of serum homocysteine and folate levels, combined with ultrasonography detection of the yolk sac, providing valuable insights for predicting the outcomes of threatened abortions [2]. The research focused on the volume ratio of sub chorionic hematoma to gestation sac using three-dimensional ultrasound in the first trimester, aiming to predict pregnancy outcomes [3].

Another study investigated how the size of sub chorionic hemorrhage impacts pregnancy outcomes, particularly in the first and second trimesters [6]. A retrospective cohort study explored the relationship between serum progesterone levels and the risk of abortion in women facing threatened abortion [7]. Additionally, a study suggested that threatened miscarriages in the first trimester correlated with an increased incidence of late pregnancy and perinatal complications [8].

Further, the research discussed the clinical diagnosis of threatened abortion and the potential role of the tumor marker CA-125 in detecting spontaneous abortion [9]. A study found an association between pet ownership during pregnancy and an increased risk of threatened abortion, particularly among specific demographic groups [10].

A population-based retrospective cohort study highlighted the elevated risks of adverse outcomes, including spontaneous abortion and preterm birth, in women with preconception infections of the genital tract [11]. An exploratory study confirmed that working women face a higher risk of adverse pregnancy outcomes, including abortion, compared to non-working women [12]. Collectively, these studies contribute to a comprehensive understanding of the multifaceted factors affecting pregnancy outcomes in cases of threatened abortion.

Generalizability

The study conducted highlights the critical role of ultrasonography in early pregnancy management. By

linking the absence of fetal heartbeat to a higher miscarriage risk, it provides valuable insights for healthcare providers worldwide, emphasizing the importance of early ultrasound in improving pregnancy outcomes. This research, reflecting on a common pregnancy complication, suggests broader applicability in enhancing clinical decision-making and patient support across various healthcare settings, thereby potentially improving care standards for pregnant women globally.

CONCLUSION

In the prospective study, ultrasonography's effectiveness in predicting outcomes for cases of threatened abortion was evaluated. Ultrasonography played a pivotal role, with 92.5% confirming viable pregnancies and 7.5% identifying non-viable ones. Notably, the absence of fetal heartbeat significantly predicted the risk of miscarriage, providing valuable insights for clinical decision-making and patient support. The study highlights the importance of ultrasonography in managing and providing reassurance for women facing threatened abortion, suggesting further research for refined risk assessment models.

Limitations

The study's limitations include the potential for selection bias, as participants were recruited from a single institution, which may limit the generalizability of the findings. Recall bias in obstetric history reporting may affect the accuracy of the data. The study's sample size may limit the ability to detect small differences in pregnancy outcomes associated with ultrasound findings.

Recommendation

Further research is warranted to refine risk assessment models and explore additional factors influencing pregnancy outcomes in threatened abortion cases.

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Conflict of interest

The authors have no competing interests to declare.

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